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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Ozawa et al.

Art Unit: 1634

Serial No.: 09/142,305

Examiner: Bradley L. Sisson

Filed: September 10, 1999

Customer No.: 21559

Title: GENE THAT IMPARTS SELECTIVE PROLIFERATIVE ACTIVITY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO RESTRICTION REQUIREMENT

In reply to the Office Communication mailed January 29, 2003, Applicants traverse the Restriction Requirement for the reasons set forth in the following remarks. Pursuant to 37 C.F.R. § 1.143, Applicants request reconsideration of this requirement, and, pursuant to 37 C.F.R. § 1.143, Applicants provisionally elect claims 1-4 and 18-24 as directed to the fusion protein GCRA(5-195, 725-726)/ER.

REMARKS

In view of Applicants' July 13, 2001 reply to the Restriction Requirement mailed June 21, 2001, claims 5-17 have been withdrawn from consideration as being directed to a non-elected invention. Claims 1-4 and 18-24, directed to fusion proteins, are currently pending in this application. These claims are the subject of an election of species requirement as discussed in detail in the following sections.

The Pending Election of Species

The Examiner asserts that the pending claims encompass a vast number of different fusion proteins. The Examiner further asserts that each different amino acid sequence of the claimed fusion proteins is considered to be a "patentably distinct" entity. Accordingly, the Examiner requires Applicants to elect a single amino acid sequence for the elected fusion protein. The Examiner also requests that Applicants amend the claims such that they will read on the elected fusion protein. Applicants respectfully disagree as follows.

Procedure

Applicants note that the present application is a 35 U.S.C. § 371 U.S. National Stage Application of PCT/JP97/00678. Thus, PCT Rules 13.1 and 13.2 should be applied to the present application. The Examiner cites to PCT Rules 13.1 and 13.2 and the issue of special technical features. Nonetheless, based on the arguments presented in the Office Action, Applicants submit that the Examiner is in fact applying U.S. restriction

rules and the test of “patentable distinction.” Thus, the restriction requirement is fundamentally flawed.

Applying the PCT Rules

Under PCT Rule 13.2, unity of invention exists when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. Further, the phrase “special technical features” refers to those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.

The Examiner’s basis for an election of species is the assertion that the claims “encompass a vast number of different fusion proteins.” The Examiner further notes that the claims do not relate to a single inventive concept because “the claimed fusion proteins all have different amino acid sequences and as such constitute patentably distinct inventions.” Applicants submit that this conclusion is in error.

A claim may encompass multiple species; this is the definition of a genus claim. In this regard, Applicants draw the Office’s attention to the administrative instructions regarding unity of invention (M.P.E.P. (Eighth Edition, August 2001) Administrative Instructions under the PCT, Appendix B), which state that unity of invention is considered only in relation to the independent claims. If the independent claims avoid the prior art and satisfy the requirements of unity of invention, no problem of lack of unity arises with respect to any claims that depend therefrom. In particular, it does not

matter if a dependent claim itself contains a further invention. Equally no problem arises in cases of a genus/species situation where the genus claim avoids the prior art.

Claim 1 is the only independent claim pending in the present application. Thus, the “special technical features” shared by the claims are defined by claim 1. As these special technical features define a contribution over the prior art, under the PCT Rules, claim 1 and its dependents satisfy the requirements of unity of invention and should be examined together in a single application.

Applying U.S. Rules

Assuming, *arguendo*, that election of species is deemed proper in this case, Applicant note that the M.P.E.P. allows the issuance of an election of species under these circumstances. Specifically, M.P.E.P. § 818.02 (b) reads as follows:

Where only generic claims are first presented and prosecuted in an application in which no election of a single invention has been made, and applicant later presents species claims to more than one species of the invention, he or she must at that time indicate an election of a single species.

Accordingly, with respect to claims 18-24, the M.P.E.P. supports the Examiner’s requirement for the election of a single embodiment for prosecution (i.e., one of the fusion proteins shown in Figure 1 - GCRER, GCRA(5-195)/ER, GCRA(5-195, 725-726)/ER). Nonetheless, Applicants submit that the Examiner’s requirement is improper in the present case for the following reasons:

First, the fact that a generic claim may encompass a number of species is not relevant. Election of a species applies to the claims and not to the disclosure.

Second, contrary to the requirements of M.P.E.P. § 809.02 (a), the Examiner has failed to identify the generic claims or indicate that no generic claims are present. In this case, claims 1-4 are clearly generic to the three specific embodiments disclosed in the specification.

Third, again contrary to the requirements of M.P.E.P. § 809.02 (a), the Examiner has failed to clearly and specifically identify each of the disclosed species to which the claims are restricted. The M.P.E.P., in § 809.02(a), expressly states that “species are preferably identified as the species of figures 1, 2, and 3 or the species of examples I, II, and III, respectively.” Merely stating a conclusion that “each different amino acid sequence of the claimed fusion protein is considered to be a patentably distinct entity” is not sufficient, particularly when not all claims are directed to “amino acid sequences.”

Finally, nothing in the M.P.E.P. supports requiring Applicants to “amend the claims such that they will read only on the elected fusion protein.” While examination of claims that do not read on the elected species is held in abeyance, Applicants submit that the claims need not be canceled or amended. Specifically, upon the allowance of a generic claim, Applicant is entitled to consideration of claims to additional species which are written in dependent form (as is the case herein) or otherwise include all the limitations of an allowed generic claim.

Summary

In short, Applicants submit that, whether viewed under the PCT Rules or U.S. Rules, the present election of species requirement is in error.

Applicants also note that the Examiner has failed to identify the species grouping. Applicants submit that the present claims are directed to at least three distinct species:

species 1 - fusion protein GCRER;

species 2 - fusion protein GCRA Δ (5-195)/ER; and

species 3 - fusion protein GCRA Δ (5-195, 725-726)/ER.

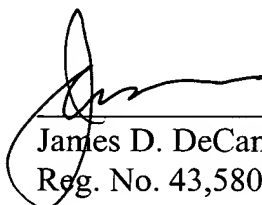
Claims 1-4 and 18 read on species 1; claims 1-4, 18-21 on species 2; and claims, 1-4 and 18-24 on species 3. In order to be responsive, the Applicants provisionally elect the fusion protein GCRA Δ (5-195, 725-726)/ER (species 3) for examination. Nonetheless, for all the reasons set forth above, Applicants request reconsideration of the restriction requirement.

Enclosed are a Petition to extend the period for replying to the Restriction Requirement for three months, to and including May 29, 2003, and a check in payment of the required extension fee.

If there are any additional charges, or any credits, please apply them to Deposit
Account No. 03-2095.

Respectfully submitted,

Date: 28 May 2003


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